IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 09-cv-02433-WJM-KLM

JOEL M. PRITCHETT,

Plaintiff,

v.

I-FLOW CORPORATION,

Defendant.

ORDER

ENTERED BY MAGISTRATE JUDGE KRISTEN L. MIX

This matter is before the Court on the **Motion of Defendant I-Flow Corporation to Exclude Dr. Suzanne Parisian** [Docket No. 89; Filed July 28, 2011] (the "Motion"). Plaintiff filed an **Opposition to Defendant I-Flow's Motion to Exclude Dr. Suzanne Parisian** [Docket No. 97; Filed August 22, 2011], and Defendant filed a **Reply in Support of Defendant I-Flow Corporation's Motion to Exclude Dr. Suzanne Parisian** [Docket No. 100; Filed September 8, 2011]. The Court held a hearing on the Motion on January 10, 2012. [#122]. The Court has reviewed the pleadings, the exhibits, the entire case file and the applicable law, and is fully advised in the premises. For the reasons set forth below, the Motion is **GRANTED in part and DENIED in part.**

I. Summary of the Case

Plaintiff had shoulder surgery in August of 2005. The surgeon used a pain pump manufactured by Defendant I-Flow to inject anesthetic into Plaintiff's shoulder joint for more

than 48 hours. Plaintiff subsequently developed a condition called "chondrolysis," which involves partial or complete loss of cartilage in the shoulder joint. Plaintiff alleges that his chondrolysis was caused by continuous injection of anesthetics into his shoulder joint, and that I-Flow manufactured and marketed the pain pump "without doing a single study to determine whether pain pump anesthetics could harm cartilage. Once on notice about the risk of shoulder chondrolysis, [I-Flow] waited years to inform physicians about the risks [and] the warnings . . . were all wholly inadequate to advise physicians about the risk of cartilage destruction." *Sched. Ord.*, [#62] at 3. Plaintiff brings claims against I-Flow for "negligence, negligent misrepresentation, fraud, strict product liability (design defect and failure to warn), breach of implied warranty and breach of express warranty." *Id.*

Defendant denies liability and causation and asserts that its "pain pumps were cleared by the FDA and were accompanied with adequate warnings and instructions." *Id.*

Plaintiff offers the expert opinion of Dr. Suzanne Parisian to testify about the federal Food and Drug Administration's ("FDA") role in regulating medical devices; how the regulations applied to Defendant; that I-Flow deviated from FDA standards in its investigation, promotion, and marketing of pain pumps; that it "did not adequately monitor and investigate performance" of the pumps; and that it did not adequately train its sales force to warn orthopedic surgeons about the risks of chondrolysis. *Expert Report S. Parisian, M.D.* (hereinafter "Parisian Report"), [#89-1] at 15-16.

Defendant asserts multiple grounds for excluding Dr. Parisian's testimony under Fed. R. Evid. 702. First, I-Flow argues that her opinions are irrelevant because the federal regulations on which she relies do not provide a standard of care regarding a medical device manufacturer's duty to warn, and because Plaintiff has made no claim for fraud on

the FDA. I-Flow contends that Dr. Parisian is unqualified to offer the opinions in her report, in that she may not opine that I-Flow violated the law, and she is not qualified to give opinions requiring technical medical knowledge in orthopedics and anesthesiology. I-Flow further objects that Dr. Parisian is not qualified to testify about I-Flow's intentions. Finally, I-Flow argues that Dr. Parisian's opinions are not reliable because she uses no methodology, regurgitates facts instead of applying a methodology to the facts, uses facts which became known after Plaintiff's surgery, bases her opinion on speculation, and mischaracterizes the law. *Motion*, [#89] at 8-20.

Not surprisingly, Plaintiff counters I-Flow's arguments by asserting that courts have routinely permitted experts like Dr. Parisian to testify that medical device manufacturers failed to comply with industry standards. Plaintiff further argues that numerous courts have approved Dr. Parisian's qualifications and allowed her testimony on similar subject matter. Plaintiff explains that he does not bring a "fraud-on-the-FDA" claim, but instead presents Dr. Parisian's testimony as proof of I-Flow's negligence in failing to meet "even minimum duties of care as imposed by parallel state and federal requirements." Plaintiff contends that Dr. Parisian will testify regarding a medical device industry standard, not a legal standard, and will opine that I-Flow failed to meet that standard. *Resp.*, [#97] at 2-22.

II. Analysis

A. General Principles of Federal Rule of Evidence 702

"Admission at trial of expert testimony is governed by Fed. R. Evid. 702, which imposes on the district court a gatekeeper function to 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *United States v.*

Gabaldon, 389 F.3d 1090, 1098 (10th Cir. 2004) (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993)). The gatekeeper function "requires the judge to assess the reasoning and methodology underlying the expert's opinion, and determine whether it is both scientifically valid and applicable to a particular set of facts." *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1221 (10th Cir. 2003). The district court's discretion in admitting or excluding expert testimony under *Daubert* is broad, "both in deciding how to assess an expert's reliability, including what procedures to utilize in making that assessment, as well as in making the ultimate determination of reliability." *Id*. at 1223.

Rule 702 provides the foundational requirements for admission of expert opinions:

> A witness who is qualified as an expert by knowledge, skill, experience, training or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Adopted in response to *Daubert*, Rule 702 was revised effective December 1, 2000 and December 1, 2011.

Under the current version of Rule 702, a witness' qualifications are no longer sufficient foundation, standing alone, to admit expert testimony. In addition to showing that the witness has appropriate qualifications, the proponent of the witness' opinions must demonstrate that the process by which the witness derived his or her opinions is reliable. *See Dodge*, 328 F.3d at 1222. To be reliable, an expert's scientific testimony must be based on scientific knowledge, which "implies a grounding in the methods and procedures

of science" based on actual knowledge, not "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Rule 702 anticipates that, if challenged, the factual foundation supporting the specific testimony will be provided by the proponent of the witness. *Dodge*, 328 F.3d at 1222. However, the proponent need not prove that "the expert is undisputably correct or that the expert's theory is 'generally accepted' in the scientific community." *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 781 (10th Cir. 1999). Instead, the proponent must show that the method used by the expert in reaching the conclusion is scientifically sound and that the opinion is based on facts which satisfy Rule 702's reliability requirements. *Id.* In the Tenth Circuit, determination of the sufficiency of the foundation for admission of expert testimony requires factual findings, preferably after an evidentiary hearing. *Dodge*, 328 F.3d at 1222.

A Rule 702 hearing is meant to address only the foundational requirement for challenged opinions, and the Court rules on only the specific challenges raised by the party opposing the opinions. *United States v. Crabbe*, 556 F. Supp. 2d 1217, 1220 (D. Colo. 2008). "The Court does not determine the weight or persuasiveness of the opinion, nor consider other evidentiary objections[, such as relevance, *etc.*,] which are more appropriately addressed at trial." *Id.* Instead, "[t]he focus . . . must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595.

1. Burden of Proof

The proponent of expert testimony bears the burden of proving the foundational requirements of Rule 702 by a preponderance of the evidence. *See Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cnty.*, 402 F.3d 1092, 1107 (11th Cir. 2005) (citing *Daubert*, 509 U.S. at 592 n.10). The proponent is not required to prove that the opinion is objectively

correct. *Mitchell*, 165 F.3d at 781. Instead, the proponent must show that the witness has sufficient expertise to choose and apply a methodology, that the methodology was reliable, that sufficient facts and data as required by the methodology were used and that the methodology was otherwise reliably applied. *Id.*; *Daubert*, 509 U.S. at 595; *see also Dodge*, 328 F.3d at 1222. The burden on the proponent of the expert is heavy, as any inadequacy in the proof on any of Rule 702's elements may render the entire opinion inadmissible. *Mitchell*, 165 F.3d at 782.

2. Rule 702 Analysis

In the Tenth Circuit, the Rule 702 analysis has two steps: (1) the Court must determine whether the expert is qualified to give the proffered opinion, and (2) the Court must examine whether the opinion itself is reliable. *103 Investors I, L.P. v. Square D Co.*, 470 F.3d 985, 990 (10th Cir. 2006). The second step of the analysis focuses on the process or means by which the witness developed the opinion, *i.e.*, the methodology or application of principles. *Id.* "This analytical framework makes the Rule 702 determination more *opinion-centric* than *expert-centric*." *Crabbe*, 556 F. Supp. 2d at 1221 (emphasis in original).

a. Qualifications

Rule 702 requires that a witness have "expert[ise resulting from] knowledge, skill, experience, training, or education," and such qualifications are considered in relation to the particular opinion or testimony proffered. *United States v. Dysart*, 705 F.2d 1247, 1252 (10th Cir. 1983). Any one of these qualifications can be sufficient to support a finding that an expert is qualified. *See* Fed. R. Evid. 702 Advisory Committee Notes, 2000

Amendments.[1] However, in some fields, experience alone is the "predominant, if not sole, basis for a great deal of reliable expert testimony." *Id.*

Some of the factors provided in *Daubert* are applicable to the question of whether the witness is sufficiently qualified. For example, the Court should consider whether the witness proposes to testify about the matters growing naturally and directly out of research he or she conducted independent of the litigation, whether the witness developed opinions expressly for purposes of testifying, and whether the field of expertise claimed by the witness is known to reach reliable results for the type of opinion the witness tends to express. *Daubert*, 509 U.S. at 595.

b. Derivation of the Opinion

Rule 702 also requires that the means or method by which the testimony or opinion is derived be reliable. As such, the Rule sets out three specific requirements: (1) a showing that the "testimony is based upon sufficient facts or data," (2) a showing that "the testimony is the product of reliable principles and methods," and (3) a showing that "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d).

i. Sufficient Facts and Data

The proponent of the opinion must first show that the witness gathered "sufficient facts and data" to formulate the opinion. In the Tenth Circuit, assessment of the sufficiency of the facts and data used by the witness is a quantitative, rather than a qualitative,

[1] Because the witness' qualifications must relate to the opinions offered in the present case, the fact that the witness has given expert testimony in other cases is not relevant unless the testimony was of the same nature using the same methodology.

analysis. Fed. R. Evid. 702, Advisory Committee Notes to 2000 Amendments; *see also United States v. Lauder*, 409 F.3d 1254, 1264 n.5 (10th Cir. 2005). That is to say, the Court does not examine whether the facts obtained by the witness are themselves reliable; whether the facts used are qualitatively reliable is a question of the weight that should be given to the opinion by the fact-finder, not the admissibility of the opinion. *Lauder*, 409 F.3d at 1264. Instead, "this inquiry examines only whether the witness obtained the amount of data that the methodology itself demands." *Crabbe*, 556 F. Supp. 2d at 1223.

ii. Methodology

Methodology, or the requirement that an opinion be derived from reliable principles or methods, involves two related inquiries: (1) identification of the methodology the witness used to reach the opinion; and (2) determination of whether the methodology is generally considered "reliable" in the field in which the expert works. *Crabbe*, 556 F. Supp. 2d at 1222. These inquiries are solely factual, and "the proponent of the opinion must establish both inquiries by sufficient, competent evidence." *Id.*

The first inquiry simply requires that the witness explain how he or she reached the opinion at issue – a simple explanation of the process normally is sufficient. *Id.* The second inquiry, whether the methodology is reliable, requires that the court assess whether that method is "scientifically valid." *Hollander v. Sandoz Pharmaceuticals Corp.*, 289 F.3d 1193, 1204 (10th Cir. 2002); *Truck Ins. Exchange v. MagneTek, Inc.*, 360 F.3d 1206, 1210 (10th Cir. 2004). A determination that a method is "scientifically valid" requires an inquiry into whether it is a scientific or logical method that can be replicated and validated. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Depending on the methodology at issue, courts have the wide discretion to consider a variety of appropriate factors in

assessing reliability. These factors, include, but are not limited to: (1) whether the methodology is one that can be tested or falsified – that is, whether the witness' approach can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the method or technique has been subject to peer review and publication; (3) whether there are known or potential rates of error with regard to the use of the method; (4) whether there are standards controlling the operation of the technique; and (5) whether the method or approach has "general acceptance" in the "relevant scientific community." *See Daubert*, 509 U.S. at 593-94, *Kumho Tire*, 526 U.S. at 149-50.

However, the above factors are not exclusive nor dispositive. *Crabbe*, 556 F. Supp. 2d at 1223. For instance, a methodology that is not peer reviewed or tested may still be considered reliable if only because it is considered a generally-accepted practice in the discipline. *See Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1235 (10th Cir. 2004). However, a methodology may have almost universal acceptance in a particular discipline, but the Court may find that the entire discipline itself (*e.g.,* astrology) is not reliable. *Kumho Tire*, 526 U.S. at 151. A court must consider and balance the factors in light of each other, and also considering the particular circumstances of the case. For example, where the methodology is unique or lacks general acceptance in the relevant field, the need for the witness to validate the theory through more extensive testing increases. *See, e.g., MagneTek*, 360 F.3d at 1212. On the other hand, an otherwise reliable methodology does not instantly become unreliable merely because the witness did not test it thoroughly in all applicable situations. *See Bitler*, 400 F.3d at 1236. Instead, once a court is satisfied that the methodology is generally reliable, suggestions that the witness should have engaged

in additional testing to achieve certainty in his or her conclusions simply go to the weight of the opinion, not its admissibility. *Id.*

iii. Application

The final step requires that the witness reliably apply the methodology to the facts and data he or she has obtained. Once again, "the requirement that the witness 'reliably' do so is not an invitation to a court to assess the worth of the opinion itself." *Crabbe*, 556 F. Supp. 2d at 1223. Instead, the Court's inquiry focuses on "whether the witness followed the dictates of the methodology in considering the facts and data." *Id.* In assessing this reliability, the Court may consider a variety of factors, including, but not limited to: (1) whether the expert employed the same degree of intellectual rigor in formulating the opinion as he or she would be expected to employ in his or her own professional life; (2) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (or, whether the gap between the analytical data and the opinion proffered is too large); and (3) whether the expert adequately accounted for obvious alternative explanations. *See generally Kumho Tire*, 526 U.S. at 152; *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Bitler*, 400 F.3d at 1233.

Finally, even if an expert is deemed qualified and his or her opinions are considered reliable, admissibility still requires a determination that the opinions are relevant. That is, the Court must consider "whether expert testimony . . . is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591 (citation omitted). Courts have routinely excluded expert testimony that was based on nothing more than speculation. *See, e.g., Jetcraft Corp. v. Flight Safety Int'l*, 16 F.3d 362, 366 (10th Cir. 1993) (expert testimony excluded as professional speculation); *Eastridge*

Dev. Co. v. Halpert Assoc., Inc., 853 F.2d 772, 783 (10th Cir. 1988) (expert testimony excluded as "tentative" and "speculative"). However, "[d]oubts about whether an expert's testimony will be useful should generally be resolved in favor of admissibility unless there are strong facts such as time or surprise favoring exclusions." *Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1083 (D. Colo. 2006) (quoting *Robinson v. Mo. Pac. R.R. Co.*, 16 F.3d 1083, 1090 (10th Cir. 1994)).

B. Admissibility of Dr. Parisian's Expert Opinions

Following an extensive review of Dr. Parisian's expert report, the Court concludes that Plaintiff has failed to sustain his burden of demonstrating the admissibility of the portions of her opinion which (1) regurgitate factual information that is better presented directly to the jury than through the testimony of an expert witness; (2) describe I-Flow's state of mind; and (3) state legal conclusions using legal terminology. In the areas identified above and described further below, Dr. Parisian's testimony is neither relevant nor reliable under *Daubert* and Rule 702.

1. Objections to Dr. Parisian's Qualifications

I-Flow asserts that Dr. Parisian's testimony should be excluded because she is not qualified to testify as indicated in her written report. I-Flow notes that she has been "excluded or sharply criticized in an eyebrow-raising number of cases." I-Flow complains about the fact that she has not practiced medicine in more than twenty years, she was employed as a medical officer at the FDA more than fifteen years ago, and her opinions do not derive from any research or experience outside of litigation. More specifically, I-Flow asserts that Dr. Parisian is not qualified to offer an opinion on whether I-Flow violated the law, she is not qualified to give opinions that require technical medical and scientific

knowledge, including knowledge related to orthopedics, anesthesiology, or chondrolysis, and she is not qualified to offer opinions about I-Flow's intentions. [#89] at 4-7, 12-16.

First, the Court agrees that Dr. Parisian is not qualified to testify regarding I-Flow's state of mind. *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011). Dr. Parisian was not employed at the FDA or at I-Flow during the time period when I-Flow sought approval of its pain pump and had no direct involvement in the FDA's review and approval process. Obviously, she therefore has no direct knowledge of I-Flow's state of mind or intent regarding development, use, marketing or promotion of the pain pump. Her written opinion is riddled with conclusory statements about I-Flow's purported knowledge and intent based on her review of documents or circumstances related to the FDA process. Inasmuch as these statements go beyond her qualifications, they are inadmissible.

Second, the Court finds that to the extent that Dr. Parisian's testimony uses legal terminology to bolster her conclusions that I-Flow violated the law, she is not qualified to do so. *See, e.g., Central Die Casting and Mfg. Co., Inc. v. Tokheim Corp.,* No. 93 C 7692, 1998 WL 812558, at *9 (N.D. Ill. Nov. 19, 1998); *Garland v. Bd. of Educ. of Denver Pub. Sch. Dist. No. 1*, No. 11-cv-00396-REB-KMT, 2012 WL 471332, at *2 (D. Colo. Feb. 14, 2012). Words – and especially the words of an expert witness – matter. Despite her regulatory experience, Dr. Parisian's impressive resume is devoid of any formal legal training or education. Although Dr. Parisian may testify about the FDA regulatory framework and may offer opinions (based on her experience) regarding whether I-Flow

complied with the regulations or not,[2] she may not express opinions about legal duties, legal conclusions, or whether I-Flow's conduct was "legal" or "illegal." Her lengthy written report occasionally lapses into unadulterated legal conclusions which are not only beyond her purview, but which usurp the important functions of the judge and jury. For example, the following paragraphs of her report contain inappropriate legal conclusions:

> ¶ 39: Even for 510(k) products, FDA clears the specific 'intended use' for a device's marketing as well as any new supported claims that can *legally* be made by the manufacturer in marketing of the device.
>
> ¶ 44: As discussed above, *the Act required* FDA to become the designated gatekeeper for the public and medical devices. It is FDA's role, not the physician's role, to first clear or approve infusion pumps combined with FDA-approved local anesthetics as intended for use together for new orthopedic continuous intra-articular infusion indications before the products can be *legally* promoted to physicians for the new indication and claims.
>
> ¶ 45: A pump label that simply indicates that a general infusion pump can be used in an 'intraoperative site,' can be misleading to various surgical specialties without full and adequate disclosure from the manufacturer and its sales force to the health care professional that ensures *compliance with the act* [sic] including accurate and updated warnings, instructions for use and discloses the limitation of data about the device.
>
> ¶ 48: As of 2011, there have been no New Drug Application or Abbreviated New Drug Application or PMA obtained to *legally* market the combination of a pain pump with local anesthetic infusion in the joint as 'intended' or indicated to be promoted to physicians as safe and effective for continuous intra-articular infusion.
>
> ¶ 49: I-Flow's promotional activities *misbranded* both its own 501(k) cleared pain pumps as well as other pharmaceutical manufacturers' NDA (ANDA) approved drugs.
>
> ¶ 68: Therefore, according to the FDA's memo, *legal* promotion of combination use of a pain pump by I-Flow would first require I-Flow to obtain clinical safety information which would be reviewed and approved by both Center for Drug Evaluation and Research and CDRH, (or the designated lead

[2] See Section 2 below.

center).

> ¶ 107: There was no reference of [sic] I-Flow's obtaining FDA approval of either an Investigational Device Exemption or Investigational New Drug Exemption to conduct the studies *legally* in the United States.
>
> ¶ 147: I-Flow, not the FDA, had a *duty* to update its labeling when aware of off-label use.
>
> Opinion No. 3 ¶ 7: I-Flow's Promotion of Pharmaceutical Manufacturers' Drugs for Unapproved Use in the Joint Space *Was Not Permitted By the Act.*

(Emphases added). This use of legal terminology and concepts to render legal conclusions is outside of Dr. Parisian's area of expertise and improperly invades the provinces of both the jury and the court. *See Garland,* 2012 WL 471332 at *2*.* To the extent that her testimony does so, it is excluded.

Finally, the Court finds that portions of Dr. Parisian's testimony would improperly invade the province of the jury by regurgitating factual information that is better presented through introduction of documents or non-expert testimony. *Hines*, 2011 WL 2680842 at *5. The Court must recognize the inherent power of expert testimony in determining whether to allow an expert to summarize documents that the jury could just as easily summarize itself. Allowing an expert witness to do so may imprint the documents with "a tilt favoring a litigant," which hinders impartial adjudication of the merits instead of promoting it. *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008). Accordingly, the portions of Dr. Parisian's testimony which summarize documents or conversations are excluded.

2. Objection to Dr. Parisian's Methodology

Rule 702(a) plainly allows the use of testimony by an expert witness with "scientific, technical *or other* specialized knowledge" (emphasis added). *Daubert* and its progeny

frequently discuss the four-factor test for determining whether an expert's methodology is "scientifically sound." *Bitler*, 400 F.3d at 1233 (holding that the factors include (1) whether a theory has been or can be tested or falsified, (2) whether the theory or technique has been subject to peer review and publication, (3) whether there are known or potential rates of error with regard to specific techniques, and (4) whether the theory or approach has "general acceptance"). Courts have also found that "the same criteria that are used to assess the reliability of a scientific opinion may be used to evaluate the reliability of non-scientific, experience-based testimony." *United States v. Frazier*, 387 F.3d 1244, 1262 (11th Cir. 2004) (citing *Kumho Tire*, 526 U.S. at 152). "In determining whether an expert's testimony is reliable, the *Daubert* factors are applicable in cases where an expert eschews reliance on any rigorous methodology and instead purports to base his opinion merely on 'experience' or 'training.'" *Clark v. Takata Corp.,* 192 F.3d 750, 758 (7th Cir. 1999).

In this Court's view, Dr. Parisian's opinions are not manifestly scientific in nature. They instead are based on her experience in working at the FDA, which involved interpreting and applying FDA "standards" or "requirements" for the medical device industry and "current quality systems." The "standards," "requirements" and "systems" referenced in her opinions are derived exclusively from applicable federal statutes and regulations. *See, e.g.,* Parisian Report, [#89-1] at 15-16.

Dr. Parisian's opinions, therefore, are primarily based on her public-sector work experience in applying federal statues and regulations to medical devices. The regulatory framework which forms the basis for her opinions is long-standing and complex. Contrary to Defendant's assertion, Dr. Parisian does not fail to use any methodology; her methodology is her training and experience in applying applicable regulations to medical

devices. In essence, she is a regulatory expert. As one District Judge on this court has pointed out in a different context, "there is nothing unusual about having [an] expert explain what applicable regulations are in place and then opine about compliance or non-compliance with those regulations." *Bullock v. Daimler Trucks N. Amer., LLC*, No. 08-cv-00491-PAB-MEH, 2010 WL 4115372, at *4 (D. Colo. Sept. 30, 2010) (unpublished decision); *see also Frederick v. Swift Transp. Co.,* 616 F.3d 1074, 1082-83 (10th Cir. 2010) (accepting expert testimony on "trucking safety [and] regulatory compliance"). Given the complexity of the medical device regulations at issue, Dr. Parisian's explanation of the regulations in place and her opinion about I-Flow's compliance or non-compliance with the regulations may be especially helpful to the jury. *See, e.g., In re Yasmin and Yaz Marketing, Sales Practices and Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2011 WL 6302287, at *19-20 (S.D. Ill. Dec. 16, 2011).

Moreover, application of the well-accepted, four-factor test for reliability of an expert's opinion also favors admission of Dr. Parisian's testimony. *See Bitler*, 400 F.3d at 1233. The first factor is not applicable, as her opinion is not susceptible to "testing." The second factor favors admission, as her opinion appears to have been "peer reviewed" in light of the fact that the textbook she authored is utilized by universities. The third factor is not applicable, as there is no known rate of error associated with the methodology used. The fourth factor favors admission, as her regulatory expertise appears to be accepted both in the scientific community and in the courts.

Accordingly, Defendant's objection to Dr. Parisian's methodology is overruled.

III. Conclusion

The **Motion of Defendant I-Flow Corporation to Exclude Dr. Suzanne Parisian** is **GRANTED in part** and **DENIED in part.** Dr. Parisian may offer testimony concerning the general regulatory requirements governing Defendant and other pain pump manufacturers, their applicability to Defendant, and Defendant's compliance or non-compliance with relevant industry or government standards. However, she may not: (1) testify about the knowledge, intent or motives of Defendant or its employees; (2) use legal terminology to express legal conclusions regarding I-Flow's conduct or duties; or (3) construct a factual narrative based on recorded evidence.

Dated: March 28, 2011

BY THE COURT:

Kristen L. Mix
United States Magistrate Judge